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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,590	09/27/2001	Yung-Ming Chen	50623.00120	4003

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EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT

PAPER NUMBER

1734

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/966,590

Applicant(s)

CHEN ET AL.

Examiner

Laura E. Edwards

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an internal/external air assisted atomizer, does not reasonably provide enablement for an internal/external atomizer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants broadly recite an internal/external atomizer in claim 1, line 4, however, the specification as originally filed only sets forth the terms, internal and external, with respect to way in which the air is fed to the nozzle. It is not clear from the specification that the internal or external description was related to the mounting of the atomizer relative to the body of applicator for applying coating to the stent. Therefore, the removal of the phrase "air assisted" in front of atomizer in claim 1 broadens the scope of the invention.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 5-8, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leidner et al (US 6,056,993) and Kirk Othmer in view of Stuffle et al (US 6,067,480).

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Leidner et al disclose a prosthetic or stent manufacturing apparatus comprising a conventional coating applicator (i.e., sprayer nozzle, extruder, etc.; see col. 10, lines 24-28 and col. 14, lines 30-47) having a body portion (area 50/51) and nozzle assembly (area 38, 39) having an outlet orifice for spraying a viscous composition including a polymer, solvent, and optionally a drug (see col. 8, lines 28-col. 9, lines 1-12) onto a mandrel (12). Leidner et al are silent concerning 1) the sprayer nozzle being an internal/external air assisted nozzle assembly and 2) a temperature controller about the nozzle assembly sized to control the temperature of the sprayed composition to prevent composition degradation. However, it was known and conventional, in the coating art, at the time the invention was made, to use as a coating applicator, an internal/external air assisted atomizing nozzle assembly to spray a viscous coating material as small droplets onto a surface as evidenced by Kirk Othmer (see page 414, "Air Atomization" to page 418, "Electrostatic Coating"). In recognition of the conventional sprayer teachings of Kirk Othmer, it would have been obvious to one of ordinary skill in the art to substitute any of the conventional sprayer systems (i.e., airless spraying, air atomization, etc.) as taught by Kirk Othmer for the coating applicator in the Leidner et al manufacturing apparatus as a means to spray the polymeric composition onto the mandrel in droplets. Furthermore, it was known in the prosthetic manufacturing art, at the time the invention was made, to provide a temperature controller or heater circumscribing the outlet orifice of a nozzle assembly in order to control the viscosity of the polymeric material dispensed therefrom as well as prevent degradation of the polymeric composition as evidenced by Stuffle et al (see col. 2, lines 1-6, col. 5, lines 12-24, and claim 5). It would have been obvious to one of ordinary skill in the art to provide a temperature controller as taught by Stuffle et al about the outlet orifice of the

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applicator as defined by the combination above in order to control the viscosity of the polymeric composition as well as prevent degradation of the polymeric composition prior to application.

With respect to claim 8, the use of a temperature modulator in the prosthetic or stent manufacturing apparatus, as defined by the combination above, is deemed to be within the level of ordinary skill in the art in order to maintain consistency in the polymeric product being made.

### ***Response to Arguments***

Applicants' arguments filed 2/6/04 have been fully considered but they are not persuasive.

Applicants contend that neither Leidner et al nor Stuffle et al teach using an atomizing air assisted nozzle assembly to spray the polymeric composition onto a stent. This argument is not deemed persuasive because Leidner et al teach the use of a conventional coating applicator or sprayer (see col. 10, lines 24-28 and col. 14, lines 30-47), which encompasses an atomizer, by dictionary definition of the term spray. As further support of evidence to that which is conventional in the coating art with respect to sprayers, the Kirk Othmer encyclopedia reference has been cited. Kirk Othmer explicitly teaches an internally/externally air supplied atomizing sprayer or nozzle assembly for applying viscous coating material in small droplets to a substrate (see page 414, "Air Atomization").

Applicants contend that neither Leidner et al or Stuffle et al teach using an atomizing air assisted nozzle assembly in combination with a temperature controller proximate the nozzle orifice to change the temperature of the of the polymeric composition. This argument is not deemed persuasive because Stuffle et al provide a temperature controller or heater operable in

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the temperature range of 180 degrees to 410 degrees (see claim 5) disposed about the outlet orifice of the nozzle assembly to maintain the dispensing of polymeric composition at a desired temperature, control the viscosity of the polymeric composition, as well as prevent the polymeric material from breakdown or degradation (see col. 3, lines 40-62 with optimized temperature ranges for dispensing the polymeric compositions in Table 2, column T sub E and col. 5, lines 12-24). It would have been obvious to one of ordinary skill in the art to provide a temperature controller or heater as taught by Stuffle et al about the nozzle orifice of the coating apparatus defined by the combination for viscosity control and prevention of composition breakdown but also to do so in accordance with the type of polymer composition used in the prosthetic manufacturing process.

Applicants contend that there is no motivation to combine the teachings of Leidner et al and Stuffle et al. This argument is not deemed persuasive because Leidner et al, the primary reference suggests biomedical prosthetic manufacture using a polymeric composition in melt form to be extruded or sprayed (see col. 9, lines 7-12) which implies that the coating applicator or dispensing device has in communication therewith heating means of some type to place the polymeric composition into melt form. One of ordinary skill in the art would appreciate and be motivated to look to known conventional coating applicators or dispensers in which polymeric, especially biomedical polymeric coating compositions are dispensed to supply the material in heated flowable form. Stuffle et al, a secondary reference provides the routine information as to how the biomedical prosthetic art, deals with polymeric compositions in melt form using a dispenser with a nozzle tip heater set at a desired temperature range based upon the polymer being used in the composition so that the composition does not degrade or breakdown (see col. 5,

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lines 12-24). Regardless of the type of dispenser used by Stuffle et al, the routineer would have found motivation to combine the heater of Stuffle et al with a conventional nozzle assembly to maintain a desired viscosity and prevent waste due to composition breakdown resulting from overheating.

Applicants contend that neither Leidner et al nor Stuffle et al recognize the problems of coating clumping, pool webs or degradation of the drug used in the composition. The Examiner acknowledges that such problems may exist, however, the apparatus as defined by the combination above would expectantly overcome said problems due to the use of the nozzle temperature controller or heater as taught by Stuffle et al. At minimum, Stuffle et al recognize the composition degradation problem and the solving of at least that problem with the heater or temperature controller (see col. 5, lines 22-24). Applicants' solving of problems has not outweighed the evidence of obviousness of the claimed structure and therefore patentability does not result.

Applicants contend that the references to Leidner et al and Stuffle are directed to fields of art completely different than the claimed invention such that one of ordinary skill in the art would not have been motivated to combine their teachings to produce the claimed invention. This argument is not deemed persuasive because both references relate to the field of biomedical prosthetic manufacture as Applicants claimed invention also relates to biomedical prosthetic manufacture. One of ordinary skill in the art would look within the field of biomedical prosthetic manufacture using a dispenser or applicator with polymeric compositions and apply the teachings of Leidner et al and Stuffle et al, which are in the same field and therefore arrive at the invention claimed.

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Applicants contend that the references are not combinable because Leidner et al teach that the coating or polymeric composition can be heated prior to spraying or dispensing and done so at a high temperature. This argument is not deemed persuasive because even though Leidner et al teach that the composition can be heated prior to spraying, placement of the heater or temperature controller as taught by Stuffle et al about the outlet orifice of the Leidner et al applicator would still enable the composition to be heated to a desired temperature prior to dispensing or spraying. As suggested by Stuffle et al, how high or low the temperature is set is based upon the polymer used in the composition.

Applicants contend that the claimed invention has shown superior results and therefore is not obvious. This argument is not deemed persuasive because while superior results have been shown, sufficient evidence also shows the claimed structure is obvious and a prima facie case of obviousness with the proper motivation has been supplied as required by Graham v. Deere. It is the Examiners position that the combination of a sprayer or atomizer, even internally or externally air assisted, with a heater or temperature controller provided on the outlet orifice to supply a polymeric composition to a substrate, whether on a mandrel or stent on the mandrel is not deemed patentable.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).




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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura E. Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Laura E. Edwards  
Primary Examiner  
Art Unit 1734

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July 2, 2004